

Michaud Calls for Hearing

Thursday, December 13 2007

WASHINGTON, DC

- Today, Congressman Mike Michaud joined with his colleagues Congressman Dan Burton (R-IN) and Tim Ryan (D-OH) in calling on the House Energy and Commerce Committee to conduct a hearing to examine the conflict of interests governing the FDA and its recent decision on failing to approve licensure of Provenge, a potentially life-saving prostate cancer drug.

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- Today, Congressman Mike Michaud joined with his colleagues Congressman Dan Burton (R-IN) and Tim Ryan (D-OH) in calling on the House Energy and Commerce Committee to conduct a hearing to examine the conflict of interests governing the FDA and its recent decision on failing to approve licensure of Provenge, a potentially life-saving prostate cancer drug.

"Many ethical questions remain about the two panelists who voted no on approving this drug," Michaud said.

"I believe that the FDA should not be appointing scientists leading the testing of a rival drug for another firm onto an advisory committee evaluating Provenge. Congress needs to get to the bottom of this. I believe we must examine conflict-of-interest issues with some medical advisers who are chosen to review drug therapies at the FDA. A full disclosure is necessary in order to restore confidence in the FDA."

The bipartisan letter requests that the Energy and Commerce Committee hold a hearing to examine possible ethical violations of these panel members considering the viability of potentially important life-saving drugs.

"We need to ensure that the FDA gets safe life-saving drugs to the market as quickly and as safely as possible," Michaud stated. "Our priority is to ensure the prompt and efficient approval of therapies such as Provenge that could potentially benefit millions of Americans with cancer."

[Letter Attached]

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December X, 2007

The Honorable John Dingell
Honorable Joe Barton

The

Chairman
Member

Ranking

Committee on Energy and Commerce Committee on Energy and Commerce

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Rayburn HOB

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Washington, DC

The Honorable Frank Pallone
Honorable Nathan Deal

The

Chairman
Member

Ranking

Subcommittee on Health
on Health

Subcommittee

Committee on Energy and Commerce Committee on Energy and Commerce

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Dear Chairman Dingell and Ranking Member Barton and
Subcommittee Chairman Pallone and Ranking Member Deal:

We are writing to express our serious concerns about the failure of the Food and Drug Administration's (FDA) to approve the licensure of Provenge, (sipuleucel-T), a potentially life-saving therapy for those suffering from advanced prostate cancer. We write to request the Committee on Energy and Commerce conduct a hearing to examine the conflict of interests governing the FDA in this decision.

While much has been written on both sides of the issue about the effectiveness of the therapy known as Provenge, there is reason to believe that serious ethics rules were violated by two FDA advisory panel members in their decision and that these violations played a role in the subsequent FDA decision to not approve Provenge at this time.

In March, the FDA's expert advisory panel (comprised of leading immunotherapy experts, oncologists, and statisticians) voted unanimously that Provenge is safe and voted 13-4 that it was effective, meeting the statutory burden of proof provided for in FDAMA for immediate licensure of Provenge while the sponsor of this therapy continued and completed its ongoing study. Overruling this panel of scientific experts, the FDA ordered additional clinical trials which won't be completed until 2010.

Prostate cancer activists have raised questions about two of the negative voters, academic medical oncologists Maha Hussain and Howard Scher. Dr. Howard Scher is lead investigator for a competing cancer drug made by Novacea and is listed as an adviser to a large venture capital firm that is also a major investor in Novacea. We believe the FDA should not be appointing scientists leading the testing of a rival drug for another firm onto an advisory committee evaluating Provenge nor should the FDA appoint an adviser to a large investor in such a competitive firm as a panel member. It is important that Congress examines possible ethical violations of these panel Members considering the viability of potentially important life-saving drugs.

A lawsuit was recently filed by Dublin, Ohio-based nonprofit Care to Live in federal court in Columbus. The lawsuit accuses FDA of ignoring conflict-of-interest issues with some medical advisers chosen to review the therapy.

Over the last few years, FDA has repeatedly failed to take substantive action to effectively restore confidence in the agency. According to its January 2007 report to Congress, the FDA granted waivers to 24 percent of the 928 members of its 47 advisory committees that met during the 14 month period from November 10, 2005 through January 4, 2007.

We believe that the FDA can and should eliminate these conflicts of interest so that everyone involved -- patients, doctors, companies, scientists, investors and the public -- believes the process has been fair and evenhanded, and the end result dictated by the science. Top-notch scientists without such substantial conflicts are available to the FDA now and are willing to serve, as noted in a recent letter to Senators Kennedy and Dodd by a number of prominent physicians, including two former editors of the New England Journal of Medicine.

The Food and Drug Administration Modernization Act of 1997 intended to make the regulatory process less arbitrary and more transparent. We must strengthen and streamline the process to ensure prompt and efficient approval of therapies such as Provenge that could potentially benefit millions of Americans with cancer.

We request your committee conduct a hearing to discuss the FDA's role in this recent decision and the conflicts of interests in the agency. Thank you for your consideration of our request.